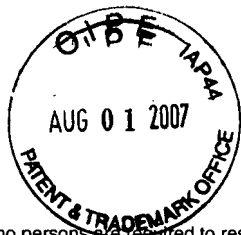


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PTO/SB/33 (07-05)

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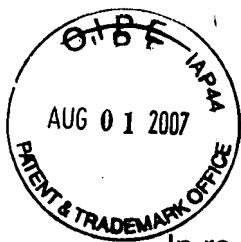
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<b>PRE-APPEAL BRIEF REQUEST FOR REVIEW</b>		Docket Number (Optional) <b>07552-0031</b>	
<p>I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]</p> <p>on _____</p> <p>Signature: _____</p> <p>Typed or printed name _____</p>		<p>Application Number <b>10/500,324</b></p>	<p>Filed <b>June 28, 2004</b></p>
		<p>First Named Inventor <b>Francesco Paolini</b></p>	
		<p>Art Unit <b>3761</b></p>	<p>Examiner <b>Philip R. Wiest</b></p>
<p>Applicant requests review of the rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a notice of appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.</p> <p>I am the</p> <div style="display: flex; justify-content: space-between;"><div style="width: 45%;"><p><input type="checkbox"/> applicant/inventor.</p><p><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.</p><p><input checked="" type="checkbox"/> attorney or agent of record. Registration number <u>50,785</u></p><p><input checked="" type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____</p></div><div style="width: 45%; text-align: center;"><p> _____ Signature</p><p><b>Aaron L. Parker</b> _____ Typed or printed name</p><p><b>202-408-4387</b> _____ Telephone number</p><p><b>August 1, 2007</b> _____ Date</p></div></div> <p>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.</p>			

<input checked="" type="checkbox"/> *Total of <u>1</u> forms are submitted.
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This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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PATENT  
Customer No. 22,852  
Attorney Docket No. 07552-0031

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:	)	
Francesco PAOLINI et al.	)	Group Art Unit: 3761
Application No.: 10/500,324	)	Examiner: Philip R. Wiest
Filed: June 28, 2004	)	Confirmation No.: 8942
For: CONTROL EQUIPMENT AND	)	
METHOD FOR AN	)	
EXTRACORPOREAL BLOOD	)	Mail Stop After Final
CIRCUIT	)	

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

Applicants request a pre-appeal brief review of the rejections set forth in the Final Office Action mailed on April 2, 2007. Applicants respectfully assert that (1) the application has been at least twice rejected; (2) this request is being filed concurrently with a Notice of Appeal; (3) this request is being filed prior to an Appeal Brief; and (4) this request is five or less pages in length, all in accordance with the guidelines set forth in the Official Gazette Notice of July 12, 2005. Applicants request the prompt review of the Examiner's rejections set forth in the Final Office Action.

**I. Status Of the Claims**

Claims 26 and 28-50 are currently pending in this Application. In the Final Office Action mailed on April 2, 2007, the Examiner rejected claims 26 and 28-50 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,561,997 to Weitzel et al. ("Weitzel") in view of U.S. Patent No. 4,894,164 to Polaschegg ("Polaschegg"), and further in view of U.S. Patent No. 6,582,387 to Derek et al. ("Derek").

**II. The Rejection of Claims 26 and 28-50 under 35 U.S.C. § 103(a) is Legally Deficient Because the Examiner Did Not Establish a *Prima Facie* Case of Obviousness**

Applicants traverse the rejections of claims 26 and 28-50 based on Weitzel in view of Polaschegg, and further in view of Derek. No *prima facie* case of obviousness has been established at least because, Weitzel, Polaschegg, and Derek, alone or in combination, fail to disclose or teach every limitation of independent claims 26 and 38.

Independent claim 26 recites “a sensor located in the access branch upstream of all blood treatment elements for measuring a first temperature of blood leaving a patient along the access branch upstream of said at least one blood treatment element” and a “temperature regulating device comprising a line conveying a fluid, said line being coupled to a portion of the return branch downstream of all blood treatment elements to form a heat exchanger directly before blood is returned to the patient.” The Examiner correctly concedes that Weitzel “does not disclose that the temperature sensor is located in the access branch, upstream of all blood treatment devices, nor does it disclose that the temperature regulating device 8 is located downstream of all blood treatment elements to form a heat exchanger directly before blood reenters the patient” (Office Action at 4), both of which are elements recited in independent claim 26. The Examiner further contends, however, that Weitzel discloses “that the heat exchanger 8 functions to keep the blood at a physiological temperature (Column 6, Lines 16-19), thus function according to a first temperature (actual blood temperature) and a reference temperature (preferred physiological blood temperature).” (April 2, 2007 Office Action at 3-4). Applicants disagree. This passage of Weitzel, cited by the Examiner, merely describes the function of a known heat exchanger, which detects the actual temperature of a fluid going through the heat exchanger. The temperature of the

fluid in the heat exchanger in Weitzel is then maintained within a predetermined range based on a reference temperature and irrespective of the blood temperature in the arterial branch as it is drawn from the patient. Nowhere does Weitzel disclose or suggest that the actual temperature of the blood, measured when it exits the patient, is used in conjunction with a reference temperature of the blood to control the temperature of the blood in a different portion of the circuit (at a location immediately upstream from the point at which the blood reenters the patient), as recited in independent claim 26. Thus, despite the Examiner's contention, Weitzel fails to disclose a "temperature regulating device for controlling the blood temperature [downstream of all blood circuit elements] by controlling the temperature of the fluid conveyed in said line as a function of said first temperature [of blood leaving a patient] **and** of a reference temperature" (emphasis added), as recited in independent claim 26.

The Examiner contends that "Polaschegg discloses a blood treatment apparatus comprising a temperature sensor 206 located in the access branch 220 and upstream of all blood treatment devices (see Figure 1)." (4/2/07 Office Action at 9.) Polaschegg, however, does not disclose a "temperature regulating device for controlling the blood temperature [downstream of all blood circuit elements] by controlling the temperature of the fluid conveyed in said line as a function of said first temperature [of blood leaving a patient] **and** of a reference temperature" (emphasis added), as recited in claim 26, and thus, fails to cure the above-mentioned deficiencies of Weitzel. Moreover, Polaschegg differs from Weitzel and the present invention in that blood temperature is controlled by warming or cooling the temperature of another fluid. In Fig. 1, dialysis fluid temperature is controlled and heat exchange occurs in dialyzer 202, while in Fig. 2, substitution fluid

temperature is controlled and heat exchange occurs at the junction between line 402 and line 221. This results in indirect temperature control, which does not occur by using a temperature regulating device downstream of all treatment elements. By only considering the position of sensor 206, the Examiner disregarded the true teaching of Polaschegg. One skilled in the art would read Polaschegg to teach indirect temperature control (i.e., controlling temperature of a different fluid using temperatures detected in the blood lines) and not temperature control of the claimed invention.

The Examiner also contends that “Derek et al. discloses a blood treatment apparatus wherein a heat exchanger may be placed within the return tube 50 (Column 10, Lines 7-11), which is downstream of all blood treatment elements (see Figure 2).” Applicants point out, however, that the cited passage in Derek is unclear and Derek fails to provide details about the components present on return tube 50 or the structure of the tube itself. Thus, Derek does not disclose a temperature regulating device located downstream of all blood circuit elements and immediately before the blood is returned to the patient, as recited in independent claim 26. Nevertheless, Derek fails to disclose or suggest a “temperature regulating device for controlling the blood temperature [downstream of all blood circuit elements] by controlling the temperature of the fluid conveyed in said line as a function of said first temperature [of blood leaving a patient] and of a reference temperature” (emphasis added), as recited in independent claim 26, and thus, fails to cure the above-mentioned deficiencies of Weitzel.

Therefore, for at least the reasons discussed above, independent claim 26 is allowable over the cited references. Accordingly, claims 28-37 are allowable at least due to their dependence from allowable independent claim 26.

For at least the reasons discussed above with respect to independent claim 26, the cited references also fail to disclose or suggest each and every limitation of amended claim 38. More specifically, the cited references do not disclose or suggest the step of "regulating a blood temperature in the extracorporeal blood circuit as a function of the first temperature [measured upstream of all blood treatment elements] **and** of a reference temperature, the blood temperature in the extracorporeal blood circuit being regulated along a portion of the return branch and downstream of all blood treatment elements, directly before blood is returned to the patient." (Emphasis added.)

Thus, independent claim 38 is allowable because the cited references do not disclose or suggest every limitation of independent claim 38. Accordingly, claims 39-50 are allowable at least due to their dependence from allowable independent claim 38.

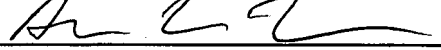
### **III. Conclusion**

For the foregoing reasons, in addition to the reasons provided in the Response filed December 21, 2006 and the Request for Consideration filed June 5, 2007, Applicants respectfully submit that the rejection of claims 26 and 28-50 includes factual and legal deficiencies entitling Applicants to a pre-appeal brief review of the Final Office Action. As such, Applicants request that the rejection be withdrawn and the claims allowed. Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

Dated: August 1, 2007

By:   
Aaron L. Parker  
Reg. No. 50,785